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Health & Group Benefits Update

Update on Issues Affecting Taft-Hartley and Single Employer Plans JANUARY 2022

Guidance Issued Through FAQs on Coverage for OTC COVID-19 Tests

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FAQs released by the Departments of Labor, Health and Human Services (HHS), and the Treasury provide guidance to group health plans regarding coverage of OTC COVID-19 tests without participant cost sharing.

On January 10, 2022, the Departments of Labor, Health and Human Services (HHS), and the Treasury (the Departments) issued FAQs pertaining to the coverage of COVID-19 self-administered or at-home tests (OTC COVID-19 tests) without an order or individualized clinical assessment by an attending healthcare provider.

The intent of this Benefits Update is to provide plan sponsors with information regarding the coverage requirements for OTC COVID-19 tests.

OVERVIEW

In March 2020, both the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act were enacted. These Acts contained requirements pertaining to COVID-19 testing coverage for group health plans and health insurance issuers. On January 10, 2022, the Departments issued further guidance through a set of FAQs pertaining to coverage of OTC COVID-19 tests.

Beginning with tests purchased on or after January 15, 2022, group health plans will be required to cover available OTC COVID-19 tests without an order of individualized clinical assessment by a healthcare provider, provided the particular test's authorization, clearance, or approval by the U.S. Food and Drug Administration (FDA) does not require such order. Plans must cover such tests without any participant cost sharing, preauthorization, or medical management, similar to how plans have been covering COVID-19 tests when the tests are ordered by an attending healthcare provider. Plans have the option to choose to cover tests that were purchased prior to January 15, 2022.

The FAQs do reiterate that COVID-19 tests (including OTC COVID-19 tests) for purposes not primarily intended for individualized diagnosis or treatment of COVID-19 (e.g., for employment purposes, etc.) are not required to be covered.

SAFE HARBOR FOR PROVIDING COVERAGE

While the FAQ does not allow a plan to limit coverage to only OTC COVID-19 tests that are provided through preferred pharmacies or other retailers, the Departments provide a safe harbor. The safe harbor relates to plans providing OTC COVID-19 tests by arranging for coverage through the plan's pharmacy network and a direct-to-consumer shipping program. Under this direct coverage approach, the participant is not required to seek reimbursement of the test costs from the plan. Rather, the plan must make the necessary changes (e.g., systems, technology, billing, etc.) such that the plan pays the test distributor directly. Further, under this direct approach plans must ensure that all participants have adequate access to OTC COVID-19 tests and are aware of details needed to access the OTC COVID-19 tests, such as dates of availability and participating retailers.

If a plan were to establish a direct-to-consumer program through partnership with its in-network pharmacies or other entities, the plan would only be required to reimburse plan participants up to $12 per test for participants who purchase OTC COVID-19 tests on their own outside of the direct-to-consumer arrangement. In these instances, the participant would have to file a claim for reimbursement to the plan.

The FAQs make it clear, however, that if a plan is unable to establish a direct coverage approach, or if there are delays that are significantly longer than the amount of time it takes to receive other items under the plans direct-to-consumer shipping programs (e.g., mail order pharmacy), then the safe harbor would not apply. If a plan cannot rely on the safe harbor, it cannot limit the amount of reimbursement paid to plan participants who obtain OTC COVID-19 tests through channels outside of the direct arrangement.

FREQUENCY LIMITS ON TESTING

The FAQs do allow for plans to limit the number of OTC COVID-19 tests without an order or individualized clinical assessment by an attending healthcare provider. The FAQs state that plans may limit the number of tests to eight per covered individual each 30-day period (or calendar month). **Plans may not limit the number of tests for a shorter period of time** (e.g., only cover four tests over 15 days).

Additionally, the FAQs do permit plans to take action to prevent suspected fraud and abuse. The FAQs outline steps plans may take, such as requiring participant attestation that the test was for personal use and not for employment purposes, or requiring participants to submit proof of purchase along with their reimbursement requests. Plans may not, however, impose on participants multilayered review processes that delay the participant's reimbursement.

DIFFERENCES BETWEEN INSURED AND SELF-FUNDED PLANS

While the FAQs do not make distinctions between insured and self-funded plans, it is our understanding that for insured plans the carrier will be the entity responsible for providing the tests and facilitating reimbursement to plan participants. For self-funded plans, the third-party administrator will be the entity in charge of processing claims for reimbursement.

IMMEDIATE CONSIDERATIONS FOR PLAN SPONSORS

Plan sponsors will need to consider several things as they work to become compliant with the guidance issued in the FAQs. The most important items to consider immediately are as follows:

1. If the plan is insured, what approach is the insured carrier taking to comply and have they communicated with the plan sponsor on what steps participants need to take to file for reimbursement?
2. For self-funded plans, will the plan seek to provide coverage through a direct arrangement and rely on the safe harbor? If so, how fast can an arrangement be executed? The plan's pharmacy benefit manager (PBM) is most likely the partner that could assist the plan in establishing a direct arrangement. Until a plan can establish a reliable direct arrangement, the safe harbor cannot be relied upon.
3. How will plans communicate these changes to participants? Plan sponsors at a minimum should likely issue a Summary of Material Modifications (SMM) outlining the new coverage and how to file for reimbursement from the plan. It may also make sense to provide participants with information on the tests (e.g., reliability of results, false positives/false negatives, how long the tests can be stored, etc.). The FAQ provides guidance on the types of information a plan could provide.
4. How will self-funded plans track the number of tests provided compared to the allowable limits set by the FAQs? The plan's third-party administrator or PBM are likely the plan partners to assist in tracking this.
5. Will the self-funded plans require an attestation from participants as part of the reimbursement process? Several testing situations other than employment, such as for travel, concert attendance, etc., would fall outside of the testing purpose as covered under the FAQ.
6. What will self-funded plans require as documentation as part of the reimbursement process? For example, will plans require documentation of the Universal Product Code (UPC) to verify that the test is covered under FFCRA?

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